

PATENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS(PCT Rule 62 and
Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)

16 January 2001 (16.01.01)

International application No.

PCT/IL99/00674

International filing date (day/month/year)

09 December 1999 (09.12.99)

Applicant

BY-PASS, INC. et al

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Charlotte ENGER

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 16 January 2001 (16.01.01)	
International application No. PCT/IL99/00674	Applicant's or agent's file reference 088/01295
International filing date (day/month/year) 09 December 1999 (09.12.99)	Priority date (day/month/year) 19 March 1999 (19.03.99)
Applicant LOSHAKOVE, Amir et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 19 October 2000 (19.10.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Charlotte ENGER Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MAIER FENSTER
FENSTER & COMPANY PATENT ATTORNEYS, LTD.
POST OFFICE BOX 10256
PETACH TIKVA, ISRAEL 49002

FENSTER & Co.

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

PTO/PCT Rec'd 17 SEP 2001

(PCT Rule 44.1)

Applicant's or agent's file reference 088/01295	Date of Mailing (day/month/year) 13 JUN 2000
International application No. PCT/IL99/00674	International filing date (day/month/year) 09 DECEMBER 1999
Applicant BY-PASS, INC.	

FOR FURTHER ACTION See paragraphs 1 and 4 below

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

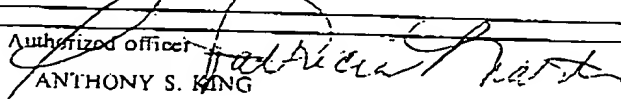
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer  ANTHONY S. KING Telephone No. (703) 306-5962
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/01295	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IL99/00674	International filing date (day/month/year) 09 DECEMBER 1999	(Earliest) Priority Date (day/month/year) 19 MARCH 1999
Applicant BY-PASS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (See Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 10A, 10B

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☒ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL99/00674

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the Abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

This invention is a device (500) for sealing a hole in a blood vessel, comprising a ring (504); a plurality of spikes (506) extending from said ring towards a center of said ring, and to first direction along an axis of said ring, said spikes being adapted for engaging a blood vessel; a plurality of tabs (502) extending substantially radially from said ring, wherein rotating said tabs around said ring distorts said ring such that said spikes are rotated in a same direction as said tabs.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL99/00674

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/00

US CL : 606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148-150, 153, 219, 221.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,234,447 A (KASTER et al.) 10 August 1993, all figures.	1-26, 32, 37, 39, 43-45
X	US 5,618,311 A (GRYSKIEWICZ) 08 April 1997, all figures.	32, 37, 39
X	US 4,917,087 A (WALSH et al.) 17 April 1990, all figures	31
X	US 5,817,113 A (GIFFORD, III et al.) 06 October 1998, all figures.	1-26
X	US 5,478,354 A (TOVEY et al.) 26 December 1995, all figures.	31, 32, 37, 39
X	US 4,485,816 A (KRUMME) 04 December 1984, all figures.	32, 37, 39



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 APRIL 2000

Date of mailing of the international search report

13 JUN 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ANTHONY S. KING

Telephone No. (703) 306-5962

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-20 and 43-45, drawn to a hole closure device, and method of using said device.

Group II, claims 21-26, drawn to a vascular access kit.

Group III, claims 27-30 and 32-36, drawn to a delivery system for a hole closure device.

Group IV, claim 31, drawn to a two part hole closure device.

Group V, claims 10-12, drawn to a method of controlling a super-elastic device.

Groups I, II, III, IV and V, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Such technical relationship among the claimed inventions involving one or more of the same contribution which the inventions made over the prior art, was not found.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/00	A1	(11) International Publication Number: WO 00/56223
		(43) International Publication Date: 28 September 2000 (28.09.00)

(21) International Application Number: PCT/IL99/00674

(22) International Filing Date: 9 December 1999 (09.12.99)

(30) Priority Data:

129067	19 March 1999 (19.03.99)	IL
PCT/IL99/00285	30 May 1999 (30.05.99)	IL
PCT/IL99/00284	30 May 1999 (30.05.99)	IL
PCT/IL99/00570	8 December 1999 (08.12.99)	IL

(71) Applicant (for all designated States except US): BY-PASS, INC. [US/US]: 40 Ramland Road, Orangeburg, NY 10962 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LOSHAKOVE, Amir [IL/IL]; P.O. Box 204, 42850 Moshav-Burgeta (IL); KILEMNIK, Ido [IL/IL]; 35 Nordau Street, 46585 Herzliya (IL); KEREN, Dvir [IL/IL]; 31 Harav Keok Street, 49315 Petach Tikva (IL).

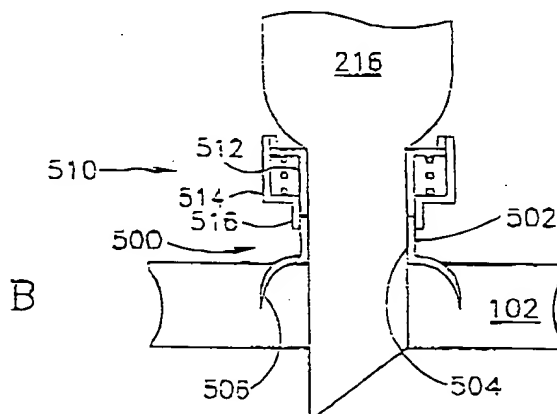
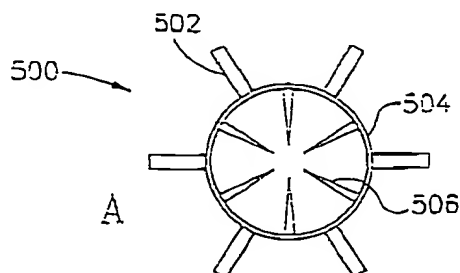
(74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P. O. Box 10256, 49002 Petach Tikva (IL).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: VASCULAR CLOSURE DEVICE



(57) Abstract

This invention is a device (500) for sealing a hole in a blood vessel, comprising a ring (504); a plurality of spikes (506) extending from said ring towards a center of said ring, and to first direction along an axis of said ring, said spikes being adapted for engaging a blood vessel; a plurality of tabs (502) extending substantially radially from said ring, wherein rotating said tabs around said ring distorts said ring such that said spikes are rotated in a same direction as said tabs.

RECEIVED

15-10-2000

FENSTER & Co.

PATENT COOPERATION TREATY

WO 00/56223
PCT/IL99/00674

From the INTERNATIONAL BUREAU

PCT Rec'd 17 SEP 2001

**NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES**

(PCT Rule 47.1(c), first sentence)

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P. O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year) 28 September 2000 (28.09.00)		
Applicant's or agent's file reference 088/01295		
IMPORTANT NOTICE		
International application No. PCT/IL99/00674	International filing date (day/month/year) 09 December 1999 (09.12.99)	Priority date (day/month/year) 19 March 1999 (19.03.99)
Applicant BY-PASS, INC. et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU, KP, KR, US



In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EA, EE, EP, ES, FI, GB, GD,
GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,
NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 September 2000 (28.09.00) under No. WO 00/56223

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT-Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer: J. Zahra Telephone No. (41-22) 338.83.38
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL99/00674

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/00

US CL : 606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148-150, 153, 219, 221.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,234,447 A (KASTER et al.) 10 August 1993, all figures.	1-26, 32, 37, 39, 43-45
X	US 5,618,311 A (GRYSKIEWICZ) 08 April 1997, all figures.	32, 37, 39
X	US 4,917,087 A (WALSH et al.) 17 April 1990, all figures	31
X	US 5,817,113 A (GIFFORD, III et al.) 06 October 1998. all figures.	1-26
X	US 5,478,354 A (TOVEY et al.) 26 December 1995. all figures.	31, 32, 37, 39
X	US 4,485,816 A (KRUMME) 04 December 1984, all figures.	32, 37, 39



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 APRIL 2000

Date of mailing of the international search report

13 JUN 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer:

ANTHONY S. KING

Telephone No. (703) 306-5962

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL99/00674

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL99/00674

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-20 and 43-45, drawn to a hole closure device, and method of using said device.

Group II, claims 21-26, drawn to a vascular access kit.

Group III, claims 27-30 and 32-36, drawn to a delivery system for a hole closure device.

Group IV, claim 31, drawn to a two part hole closure device.

Group V, claims 10-12, drawn to a method of controlling a super-elastic device.

Groups I, II, III, IV and V, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Such technical relationship among the claimed inventions involving one or more of the same contribution which the inventions made over the prior art, was not found.

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61B 17/00	A1	(11) International Publication Number: WO 00/56223 (43) International Publication Date: 28 September 2000 (28.09.00)
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(21) International Application Number: PCT/IL99/00674

(22) International Filing Date: 9 December 1999 (09.12.99)

(30) Priority Data:

129067	19 March 1999 (19.03.99)	IL
PCT/IL99/00285	30 May 1999 (30.05.99)	IL
PCT/IL99/00284	30 May 1999 (30.05.99)	IL
PCT/IL99/00670	8 December 1999 (08.12.99)	IL

(71) Applicant (for all designated States except US): BY-PASS, INC. [US/US]; 40 Ramland Road, Orangeburg, NY 10962 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LOSHAKOVE, Amir [IL/IL]; P.O. Box 204, 42860 Moshav-Burgeta (IL). KILEMNIK, Ido [IL/IL]; 35 Nordau Street, 46585 Herzelia (IL). KEREN, Dvir [IL/IL]; 31 Harav Kook Street, 49315 Petach Tikva (IL).

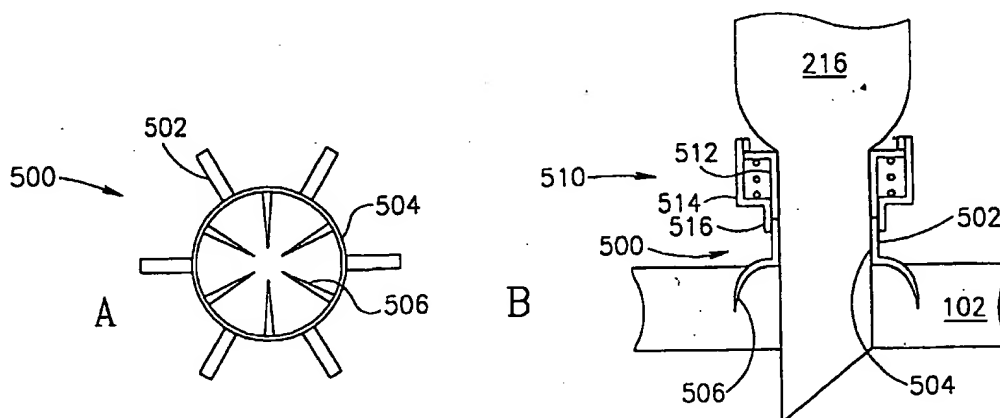
(74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P. O. Box 10256, 49002 Petach Tikva (IL).

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(54) Title: VASCULAR CLOSURE DEVICE



(57) Abstract

This invention is a device (500) for sealing a hole in a blood vessel, comprising a ring (504); a plurality of spikes (506) extending from said ring towards a center of said ring, and to first direction along an axis of said ring, said spikes being adapted for engaging a blood vessel; a plurality of tabs (502) extending substantially radially from said ring, wherein rotating said tabs around said ring distorts said ring such that said spikes are rotated in a same direction as said tabs.

VASCULAR CLOSURE DEVICE**RELATED APPLICATIONS**

This application is a Continuation-in-part of PCT application PCT/IL99/000284, of PCT application PCT/IL99/00285 and of a PCT application titled "Vascular Surgery", attorney
5 docket 088/01161, all of which designate the US, the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to vascular devices and especially to sealing vascular incisions.

BACKGROUND OF THE INVENTION

10 There are many medical procedures in which a tube is temporarily inserted into- or out of- a blood vessel. One particular example is the use of a heart-lung machine during heart surgery. A first cannula is inserted into the aorta to return blood after it was oxygenated by the heart-lung machine. One or more second cannulas are inserted into the vena cava or the right
15 atria. When the heart surgery is completed, the two cannulas are removed and the holes in the vena cava and aorta are closed using a "purse-string" suture, in which a single thread is stitched to surround the hole and then pulled tight (like a purse-string) to close the hole. Performing this suture requires skill and practice. In addition, it may be difficult to perform the suturing in a key-hole procedure or in other types of surgery where there is limited access to
20 the wound site. Typically, the suture is attached as soon as the cannula is inserted into the body.

Another type of temporary tube insertion occurs during a failed anastomosis procedure. If the joining of two blood vessels fails, the point at which an opening (if any) was formed in one of the blood vessels, must be sutured shut, also possibly using a purse string.

25 Vascular ports, for example for the introduction of a catheter into a femoral artery, are known. Once the procedure is completed, the port is usually removed and the hole formed by the port is either sutured or closed using manual pressure. These ports are generally applied through the skin or a small incision and remain mostly outside the body.

US patent 5,478,354, the disclosure of which is incorporated herein by reference,
30 relates to a the field of closing non-linear surgical incisions, in fascia and/or skin, using a single fastener and describes various devices for closing such non-linear surgical incisions.

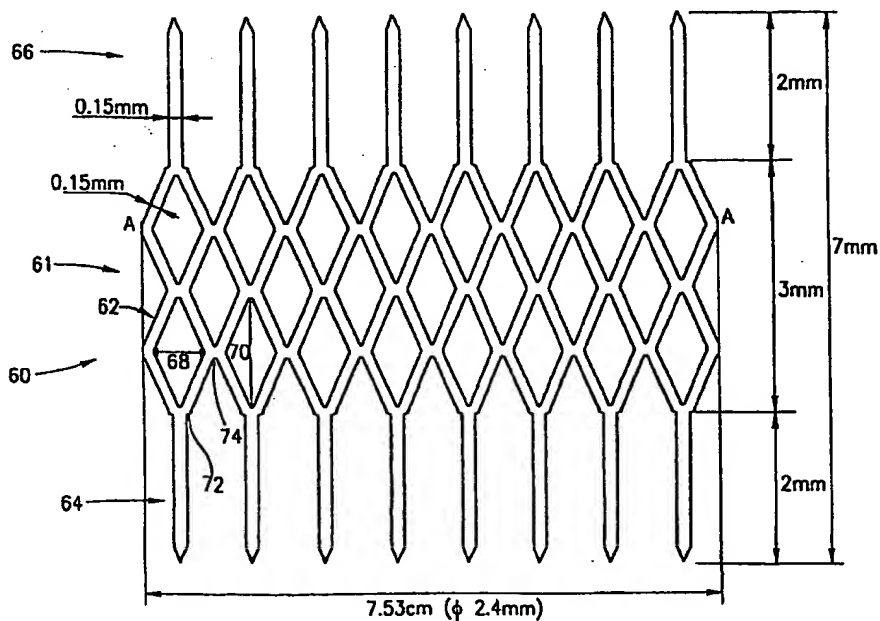
SUMMARY OF THE INVENTION

An aspect of some preferred embodiments of the invention relates to a closure device for sealing a vascular incision. In some embodiments, the device may also function as an



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(21) International Application Number: PCT/IL99/00284 (22) International Filing Date: 30 May 1999 (30.05.99) (30) Priority Data: 124694 29 May 1998 (29.05.98) IL 129067 19 March 1999 (19.03.99) IL (71) Applicant (for all designated States except US): BY-PASS, LTD. [IL/IL]; Hasadnaot Street 3, 46728 Herzelia B (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): DEROWE, Ari [IL/IL]; Moshav Salit, 45885 Hasharon Hatichon (IL). LOSHAKOVE, Amir [IL/IL]; P.O. Box 204, 42860 Moshav Burgeta (IL). (74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P.O. Box 10256, 49002 Petach Tikva (IL).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: METHODS AND DEVICES FOR VASCULAR SURGERY**(57) Abstract**

An anastomotic connector (60) for attaching two blood vessels, comprising a cylinder-like portion having a lumen, two ends, and an array of cells elements, and a tissue engaging portion (60) comprising at least one set of spikes (64) wherein at least one spike arranged adjacent one of the two ends of said cylinder-like portion. The connector (60) may comprise at least a second set of spikes (66) adjacent the other of the two ends.

METHODS AND DEVICES FOR VASCULAR SURGERY**FIELD OF THE INVENTION**

The present invention relates to performing an anastomosis and especially to an anastomosis relating to percutaneous bypass surgery.

BACKGROUND OF THE INVENTION

5 Connecting two blood vessels, anastomosis, is an important surgical technique for reconstructive, therapeutic and cosmetic surgery. The gold standard of anastomosis is manual suturing of the two blood vessels in a side-to-side, end-to-end or end-to-side configuration. Although it is generally desirable to shorten the length of any surgical procedure, this is
10 especially important in coronary bypass surgery, for example minimally invasive procedures in which the heart continues beating and open surgical procedures in which a patient is often attached to a heart-lung machine and his heart is stopped.

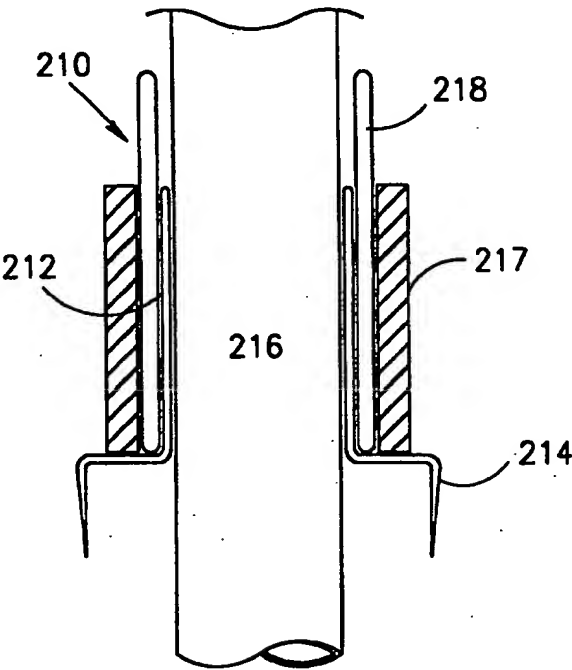
In addition to manual suturing of blood vessels, other methods of attaching two blood vessels are known, including method using staples and anastomosis rings. PCT publications
15 WO 97/40754 and WO 97/28749, the disclosures of which are incorporated herein by reference, describe various staplers for coronary bypass surgery, wherein a graft is connected on one of its ends to the aorta and at its other end to an occluded coronary artery, distal to the occlusion. In this type of surgery, the anastomosis is sealed by stapling the graft to the aorta, while pressing both aorta and graft against an anvil. In one publication, the anvil is inserted
20 into the aorta for the stapling and then removed, possibly by taking the anvil apart. In the other publication, the end of the graft is everted over a ring-shaped anvil, so that the anvil is outside of the blood vessel at all times.

Recently, bypass surgery has been performed using minimally invasive (e.g., key-hole and mini-thoractomy) surgery. In this type of surgery, a small hole is made in the chest,
25 instead of cracking open the ribs, and the mammary arteries are used for bypass grafts. The suturing and/or stapling is performed using tools, for example such as those described above.

An even less invasive type of surgery requires no opening of the chest at all. Rather, one or more catheters are introduced into the blood vessels using a percutaneous approach. PCT publications WO 97/27898, WO 97/13471 and WO 97/13463 and their priority
30 documents, namely U.S. applications, 60/010,614, 60/005,164, 08/730,327 and 08/730,496, the disclosures of which are incorporated herein by reference and termed the "Transvascular Applications", describe methods and apparatus for percutaneous treatment of arterial occlusions. Two main methods are taught in these applications. In one method, a tunnel is excavated within tissue (outside the vessel) from one side of the occlusion to the other side of

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: VASCULAR PORT DEVICE (57) Abstract <p>This invention is a device (210) for sealing a hole (100) in a blood vessel (102), comprising a blood vessel engager (217) having at least one spike (214), for engaging a portion of a blood vessel (102) adjacent a hole in the blood vessel, and a body (216) coupled to the blood vessel engager (217). The device (210) has at least two configurations, a first configuration in which the device does not seal the hole, and a second configuration to which the device can be changed so that the second configuration of the device seals the hole.</p> 		

VASCULAR PORT DEVICE**FIELD OF THE INVENTION**

The present invention relates to vascular devices and especially to sealing vascular devices.

BACKGROUND OF THE INVENTION

5 There are many medical procedures in which a tube is temporarily inserted into- or out of- a blood vessel. One particular example is the use of a heart-lung machine during heart surgery. A first cannula is inserted into the aorta to return blood after it was oxygenated by the heart-lung machine. One or more second cannulas are inserted into the vena cava or the right
10 atria. When the heart surgery is completed, the two cannulas are removed and the holes in the vena cava and aorta are closed using a "purse-string" suture, in which a single thread is stitched to surround the hole and then pulled tight (like a purse-string) to close the hole. Performing this suture requires skill and practice. In addition, it may be difficult to perform the suturing in a key-hole procedure or in other types of surgery where there is limited access to
15 the wound site. Typically, the suture is attached as soon as the cannula is inserted into the body.

Another type of temporary tube insertion occurs during a failed anastomosis procedure. If the joining of two blood vessels fails, the point at which an opening (if any) was formed in one of the blood vessels, must be sutured shut, also possibly using a purse string.

20 Vascular ports, for example for the introduction of a catheter into a femoral artery, are known. Once the procedure is completed, the port is usually removed and the hole formed by the port is either sutured or closed using manual pressure. These ports are generally applied through the skin or a small incision and remain mostly outside the body.

SUMMARY OF THE INVENTION

25 An aspect of some preferred embodiments of the invention relates to a self-sealing anastomotic device. In a preferred embodiment of the invention, if an anastomosis cannot or is not completed, the device seals any opening in the vessel to which the device is connected. In a preferred embodiment of the invention, the device seals the opening by forcing the lips of the opening against each other or against a part of the device. Alternatively, the device seals the
30 opening by forcing portions of the device against each other. In some embodiments of the invention, the anastomosis device severs a portion of one of the vessels of the anastomosis, for example an "end" vessel in an end-to-side anastomosis. Alternatively or additionally, the device, when it seals the opening, engages a larger portion of the blood vessel to which it is attached, to form a seal.

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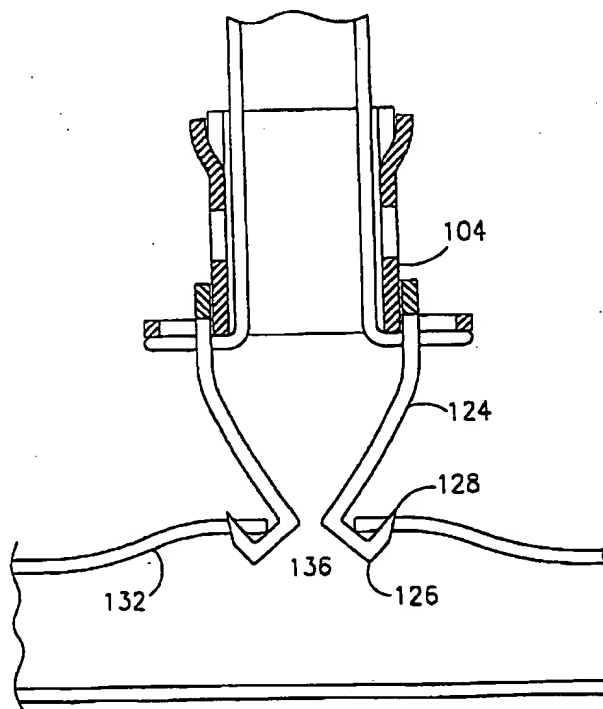
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(54) Title: VASCULAR SURGERY

(57) Abstract

An anastomotic connector for connecting a graft to a target vessel, comprising a thin collar section (104) adapted to engage a portion of the graft; and a separate spike section (124) adapted to mount on said collar section, and comprising a plurality of spikes (126) each of said spikes (126) adapted to transfix said graft. Preferably, the connector comprises at least one locking element for interlocking said spike section (124), and said collar section (104). Preferably the locking element provides a spring action between the two sections.



VASCULAR SURGERY
RELATED APPLICATIONS

This application is a Continuation-in-part of PCT application PCT/IL99/000284 and of PCT application PCT/IL99/00285, both of which designate the US, the disclosures of which
5 are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to performing anastomosis of blood vessels.

BACKGROUND OF THE INVENTION

Connecting two blood vessels, anastomosis, is an important surgical technique for
10 reconstructive, therapeutic and cosmetic surgery. The gold standard of anastomosis is manual suturing of the two blood vessels in a side to side, end to end or end-to-side configuration. Although it is generally desirable to shorten the length of any surgical procedure, this is especially important in coronary bypass surgery, in which a patient is usually attached to a heart-lung machine and his heart is often stopped.

15 In addition to manual suturing of blood vessels, other methods of attaching two blood vessels are known, including, staples and anastomosis rings. PCT publications WO 97/40754 and WO 97/28749, the disclosures of which are incorporated herein by reference, describe staplers for coronary bypass surgery, wherein a graft is connected on one of its ends to the aorta and at its other end to an occluded coronary artery, distal to the occlusion. In this type of
20 surgery, the anastomosis is sealed by stapling the graft to the aorta, while pressing both aorta and graft against an anvil. In one publication, the anvil is inserted into the aorta for the stapling and then removed, possibly by taking the anvil apart. In the other publication, the end of the graft is everted over a ring-shaped anvil, so that the anvil is outside of the blood vessel at all times.

25 Recently, bypass surgery has been performed using minimally invasive (key-hole) surgery. In this type of surgery, a small hole is made in the chest, instead of cracking open the ribs, and the mammary arteries (e.g., LIMA, RIMA) are used for bypass grafts. The suturing and/or stapling is performed using tools, for example as described above.

An even less invasive type of surgery requires no opening of the chest at all, rather, one
30 or more catheters are introduced into the blood vessels using a percutaneous approach. PCT publications WO 97/27898, WO 97/13471 and WO 97/13463 and their priority documents, namely U.S. applications, 60/010,614, 60/005,164, 08/730,327 and 08/730,496, the disclosures of which are incorporated herein by reference and termed the "Transvascular Applications", describe method and apparatus for percutaneous treatment of arterial occlusions. Two main